October 17, 2002

Mr. David E. Carter
Chair, National Organic Standards Board,
and Members of the Board
c/o National Organic Program
Agricultural Marketing Service
U.S. Department of Agriculture
Washington, DC 20250

Re: Should Ion Exchange Resin Beads That Are Not "Processing Aids" Require Review by the National Organic Standards Board As "Ingredients" for the National List, Section 205.605?

Dear Mr. Carter and Members of the Board:

At the meeting of the Board on October 19-20, 2002, the Board will take up the question of which materials used in processing should be reviewed for the National List, Section 205.605, and make a recommendation on this subject to the National Organic Program. We wish to commend the Board for appointing a Task Force to address this important, timely question.

As you are aware, our company, Colorado Sweet Gold LLC, intends to manufacture an organic high fructose corn sweetener (HFCS) at its plant in Johnstown, Colorado. Ion exchange purification is an integral, essential process in corn sweetener manufacturing. Ion exchange is an accepted organic practice that is permitted under the National Organic Program, the EU regulations and the IFOAM 2002 Basic Standards. At the heart of the ion exchange process we will use is a filter that would consist of synthetic resin beads. Ion exchange depends entirely on the resin beads. Without them there is no ion exchange process.

These resin beads are not a "processing aid" but are a fixed component of the process equipment itself. The FDA has recently said it will treat all ion exchange resins as "food contact

substances" rather than as "secondary direct food additives," in recognition of the fact that ion exchange resins are "not intended to have any technical effect in food," thus clearly distinguishing ion exchange resins from "processing aids." The Board must now decide for the first time in a formal policy whether it should review synthetic substances of this type, those which come in contact with food solely as part of the equipment in the process of manufacturing, not as "processing aids."

We respectfully request that the Board consider two alternative proposals in making its recommendation:

Our first proposal would be simply to follow the FDA's practice, in which ion exchange resins are considered "food contact substances," and exempt all "food contact substances" from the Board's review. As "food contact substances," ion exchange resins are in the same category as other materials used in manufacturing, packing, packaging, transporting and holding food that are not used with the intent to have any technical effect on food. Therefore, the Board would be able to deal with all these materials, including ion exchange resins, by making "food contact substances" exempt from Board review for the National List.

Our alternative proposal would be to impose the following threshold test: Any synthetic substance used in processing that comes in contact with food but meets the following three conditions should not be subject to the Board's review:

(a) It is not added to the food for any technical or functional effect.
(b) It is not a "processing aid" as defined in the Final Rule, Section 205.2, and
(c) It is not present in the finished food at concentrations above 0.05 parts per million.

If the concentration of the synthetic substance in finished food is below this extremely low level, this means that the level of migration would be considered de minimis. If the concentration is above this level, then the substance could not be used in organic processing without being added to the National List through a petition to the Board. Thus the Board would retain review authority over packaging and processing materials that might release constituents to the processed food if the concentrations were of a significant amount. To determine whether a synthetic substance was below the threshold, processors could supply appropriate documentation to their certifiers.

In short, we are talking about synthetic substances in equipment and packaging that come in contact with food but are not intended to be present in the food or to act as "processing aids." While these substances have no purpose in the food, they are, however, capable of migrating at extremely low levels into the food that they contact.

It is widely recognized that materials that come into contact with food will release some constituents into the processed food. The amount of material that is found to migrate is dependent upon the time and temperature of the contact, the nature of the food, and the nature of the processing material. However, while the level of migration may be reduced, basic chemical thermodynamics tells us that it will never be completely eliminated. We do not see how it is practical for the Board to attempt to review all materials that contact organic foods.

This is why we are making our two alternative proposals. The first would be for the Board to exclude the whole FDA category of "food contact substances" from its review**.** The second would be for the Board to establish a minimal level of interest, *i.e*. a de minimis concentration, a threshold of 0.05 parts per million, below which the presence of materials is deemed to be insignificant.

Regardless of which of these two approaches the Board would choose, the resulting policy would be that substances that come in contact with food in the manufacturing and packaging process, such as ion exchange resins, but merely migrate into the food at minimal levels, will not have to be reviewed by the Board. As a practical matter, such a policy is necessary to allow the Board to devote its scarce time and resources to the review of the more critical non-organic materials. We feel that such a policy, reached through either approach, would be entirely consistent with organic principles and would receive the support of the organic processing community.

The need for such a policy was underscored last month when the Board met and approved activated charcoal for processing on the National List at Section 205.605. The Board's discussion of this material suggested that it was proper for this substance to have been petitioned to the Board because while it was a filtering substance rather than an "ingredient," the controlling factor was that it came into direct contact with the food. In our view the Board was newly stretching its concept of "ingredient" to apply to substances that merely come into contact with food, whether or not they are intended to go into the food for a functional or technical effect.

If direct contact with food becomes the criterion for Board review, a wide variety of synthetics present in processing, including our resin beads, would be required to be petitioned to the Board for inclusion in Section 205.605. Aside from ion exchange resins, there are numerous synthetics used in organic food processing that are neither "processing aids" nor intended as "ingredients." Examples are: synthetic materials in numerous types of equipment, such as rubber and plastic piping; plastics used in rigid tubs for yogurt, butter, margarine and cottage cheese; polyethylene terephthalate (PET) used in dual-ovenable microwave dinner trays; drink boxes and freezer bags, and the food packaging films used for wrapping meat and frozen food. All of these synthetic materials have direct contact with food and entail migration into the food at extremely low levels measured in parts per billion. The potential of migration from the ion exchange beads used in our process is at the low end of the range of the migration found in these materials.

The Board has never before treated such materials as “ingredients” or as "processing aids" that must be considered for the National List. To require now that they be reviewed by the Board would cause disruption and confusion among processors and their certifiers, raising serious issues of certification and labeling, just as the Final Rule is being fully implemented beginning October 21.

We will now discuss in more detail the justification for our proposals. We will explain:

- How the Board's recommendation will affect our company.
- How our resin beads are not "processing aids" but merely migrate into food at de minimis levels from contact with the food.
- How the Board has never specifically considered whether it should review substances that merely migrate into food due to contact.

I. HOW THE BOARD'S RECOMMENDATION WILL AFFECT OUR COMPANY

For more than a year our company has been making significant financial commitments to start the first corn processing plant in North America to manufacture organic starch and HFCS. We have an exciting story to tell about our project. In a separate letter to the Board, we will be providing you with further background information on our company, including, among other matters, figures on the supplies of domestically-raised organically grown corn that our plant will be utilizing.

We are coming before the Board in the hope that the Board will help us clear the largest hurdle confronting our project. This is the uncertainty over whether our ion exchange resin beads will be organically acceptable. On December 5, 2001, the Processing Committee of the Board issued guidelines proposing that certain processes, including ion exchange, be subject to review by the Board. While this proposal did not attract a consensus of industry support and has never been finalized, it caused our certifier to decide not to continue our organic certification until the status of our process could be resolved. Since last December this has had a negative impact on our ability to secure financing from equity investors and lenders.

The recommendation that the Board makes will have a direct impact on our company. If the Board recommends that substances such as our resin beads should not require review for the National List, and the Department agrees, then our plant can be certified immediately and we can proceed to produce and market our organic product. We can take advantage of the time between now and February 2003 to make forward contracts for organic corn in the 2003 harvest.

On the other hand, if the Board recommends that it should review substances such as our resin beads, and the Department supports this conclusion, then our company will not be able to proceed unless it files a petition with the Board for the ion exchange filter. This means we would miss the opportunity to make forward contracts for organic corn this year. If we are forced to buy

our first year of corn on the spot market, this will not give us a viable business situation for equipping and starting up our plant. It is doubtful than we can sustain our project for the additional length of time that a petition would take. This will result in a lost investment as well as lost opportunities for the U.S. organic industry and U.S. organic corn growers.

II. OUR RESIN BEADS ARE NOT "PROCESSING AIDS" BUT MERELY MIGRATE INTO FOOD AT DE MINIMIS LEVELS FROM CONTACT WITH THE FOOD.

The ion exchange filtering process is essential to the manufacture of organic HFCS. Its purpose is to filter out minerals, salts, proteins and color bodies from the water portion of the corn syrup process stream. It has been organically certified in Europe and therefore accepted by certifiers in the United States. While the National Organic Program Final Rule does not prohibit ion exchange as a process, the question has arisen over the synthetic resin beads that we intend to use as our filter. The issue is whether these resin beads are an "ingredient in or on" processed food that would have to be petitioned to the Board for the National List, Section 205.605.

Until this question is resolved either by the Board or by the National Organic Program, our certifier has informed us that it will not be able to continue our certification, and this is why our project has been on hold.

As we have already noted, while "processing aids" have to be petitioned under Section 205.605, our resin is not a "processing aid." Instead it is part of the process itself, a stationary component of the filtering equipment. Both the FDA (21 CFR § 101.100(a)(3)(ii)(c)) and the National Organic Program Final Rule (7 CFR § 205.2), which adopted the FDA's definition, define a "processing aid" as a substance that is added to food for its technical or functional effect. Our resin is intended to stay in the filter and not go into the food for any purpose.

In 21 CFR § 101.100(a)(3), the FDA makes an express distinction between "incidental additives" that are "processing aids" and "incidental additives" that are "substances migrating to food from equipment and packaging." Our ion exchange resin beads are "incidental additives" because they will migrate into food from equipment. Other "incidental additives" will migrate into food from packaging materials. This does not make them "processing aids."

Similarly, these ion exchange resin beads do not fit within the definition of "processing aids" in the FDA food additive regulations, at 21 CFR § 170.3(o)(24). That regulation defines "processing aids" as "Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculents, filter aids, and crystallization inhibitors, etc." The ion exchange resin beads are not "agents" or "aids" that are intentionally added to the food. In our case they are a material used in a stationary filter, and this makes them equipment, not a "filter aid" or any other "processing aid."

The FDA has recently clarified its position on ion exchange resins specifically, and this clarification should be quite helpful to the Board in understanding how the FDA views ion exchange resins.

In the CFR, the FDA has been listing our resin at 21 CFR § 173.25(a)(1) as a "secondary direct food additive" permitted in food. This designation has led some to assume that our resin would be an intentional component of the corn sweetener. However, the FDA has now made it clear that it considers ion exchange resins to be "food contact substances." These are defined in the Federal Food, Drug, and Cosmetic Act as substances "intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in food." 21 U.S.Code § 348(h)(6).

This means that the FDA will treat ion exchange resins as it treats packaging materials, treating both as "food contact substances." In practical terms, this means that before a new packaging material or ion exchange resin may be used in contact with food, the suppliers must file a Food Contact Notification (FCN) rather than the Food Additive Petition required for food ingredients.

This is not a sudden change, because the FDA has acknowledged for some time that the substances it has been listing as "secondary direct food additives" have in fact been more like food contact substances. Now it has officially clarified that ion exchange resins are subject to FCNs instead of Food Additive Petitions. This was disclosed by an FDA official in the Office of Food Additive Safety on October 15, 2002, during an FDA seminar on food contact notifications.

The migration of our resin occurs only at extremely low de minimis levels at which it cannot possibly affect the character of the food. This is why the FDA has decided to consider ion exchange resins as "food contact substances." To determine the exact extent of this migration, in June 2002 we had the Food Protein Research and Development Center at Texas A&M University conduct extractives testing of our resin. The tests revealed that migration would be only at the rate of around 40 parts per billion. When the corn sweetener is incorporated into finished food, the effect of the resin would be only one part per billion of daily dietary intake. This is less than the dietary exposure that occurs from other substances in food processing equipment and from common packaging materials.

In response to concern in some organic circles about filtration techniques used in processing, the 2002 Final Draft of the IFOAM Basic Standards for Organic Production and Processing contains a provision, Section 6.3.4 that would place restrictions on "filtration techniques that chemically react with or modify organic food on a molecular basis." This policy would be carried out by restrictions on certain techniques and materials, such as "certain ion exchange resins and absorption techniques."

The provision also prohibits asbestos in filtration equipment, as well as any "techniques or substances that may negatively affect the product." We are confident that our ion exchange process and the particular resin we would use would comply with this latest IFOAM standard.

Our resin, then, is not a "processing aid" and is no more an "ingredient" than other synthetic materials that migrate into food in minuscule quantities from equipment or packaging. The FDA regards ion exchange resins as "food contact substances" in the same category as materials used in equipment or packaging. This is why we believe it would be appropriate for the Board to accept either of our two alternative proposals as a basis for the Board's not having to review such substances.

III. THE BOARD HAS NEVER SPECIFICALLY CONSIDERED WHETHER IT SHOULD REVIEW SUBSTANCES THAT MERELY MIGRATE INTO FOOD DUE TO CONTACT.

The substances that we are discussing are those that are not intentionally placed in the food but merely migrate into food in very small amounts as a result of contact. It is notable that the Board has never specifically considered whether it should review these substances for the National List. Nor is there any guidance on this question to be found in the Final Rule or the Preamble.

This means that it is up to this Board to decide this question for the first time. We hope that the Board will consider the proposal that we are making.

In its food labeling regulation, the FDA lists as "incidental additives" a total of three distinct categories: "substances that have no technical or functional effect but are present in a food" at insignificant levels because they were "incorporated into the food as an ingredient of another food…." (21 CFR § 101.100(a)(3)(i)), "processing aids" (21 CFR § 101.100(a)(3)(ii)(a)-(c)) and "substances migrating to food from equipment or packaging." (21 CFR § 101.100(a)(3)(iii)).

On October 31, 1995, the Board issued a recommendation, "Final Recommendation Addendum Number 15, Incidental Food Additives in Organic Foods." (A copy of this recommendation is enclosed.) This recommendation was the Board's careful response to the FDA food labeling regulation on "incidental additives", 21 CFR § 101.100(a)(3). The Board pointed out that while the FDA did not require "incidental additives" to appear on the food label of any foods, including organic foods, for organic foods "these additives must be subjected to the same National list evaluation process as other processed food ingredients."

However, the Board's specific recommendation dealt only with one of the three categories, "processing aids." By singling out "processing aids," the Board therefore did not make any specific recommendation for National List coverage of either of the other two "incidental additives": those

substances that were "incorporated into the food as an ingredient of another food" and "substances migrating to food from equipment or packaging."

In the Board's introduction, it said that the FDA's regulation on "incidental food additives" included two categories, the substances "incorporated into the food" and the "processing aids." The Board's recommendation completely omitted any specific discussion or even mention of the FDA's third category of "incidental additives," the "substances migrating to food from equipment or packaging."

The Board in 1995 had evidently read the entire FDA food labeling regulation at 21 CFR § 101.100(a)(3) and was familiar with its meaning. In its recommendation it chose to mention only two of the three kinds of "incidental additives" that the FDA had identified in 21 CFR § 101.100(a)(3). It failed even to mention the third kind of incidental additive, "substances migrating from equipment or packaging." This was a glaring omission. What it indicates is that the Board did not choose to take a position for or against including these substances in its review. This is why the 1995 recommendation does not give the current Board any precedent to follow in deciding whether it should review "substances migrating from equipment and packaging."

Turning to the Final Rule and its Preamble, they too leave only a blank slate for the Board to follow. "Processing aids" are well defined in the Final Rule, at 7 CFR § 205.2, adopting the same definition of "processing aid" that the FDA food labeling regulation uses at 21 CFR § 101.100(a)(3)(ii)(a)-(c). However, aside from this definition of "processing aid," neither the Final Rule nor the Preamble define or mention any other type of "incidental additive" or "incidental food additive."

The Rule itself does not mention "incidental additives" or "incidental food additives." The Preamble uses the term "incidental food additive" only twice throughout its entire length, at pages 80577 and 80587. Neither of these vague, fleeting references gives any support to a claim that the drafters of the Preamble intended to cover "substances migrating from equipment or packaging" under the National List.

IV. IV. CONCLUSION

We hope that the two alternative proposals and accompanying information that we have presented will be of constructive value to the Board as it considers its recommendation for which materials used in processing it should review for inclusion on the National List under Section 205.605.

Sincerely yours,

Charlie Gilbert, Chief Executive Officer
Ken Chambers, Chief Operating Officer

Enclosure